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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			KIM, ALEXANDER D	
			ART UNIT	PAPER NUMBER

1656

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/613,541

Applicant(s)

SCHOFIELD ET AL.

Examiner

Alexander D. Kim

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. Claims 1-15 are pending in the instant case.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, 6-7, drawn to an isopenicillin N synthase (IPNS) optionally in the form of a complex with Fe and a substrate, classified in class 530, subclass 350.
 - II. Claims 4-5, drawn to use of the three dimensional structure of IPNS, classified in class 702, subclass 19.
 - III. Claims 4-5, drawn to use of the three dimensional structure of DAOCS, classified in class 702, subclass 19.
 - IV. Claims 4-5, drawn to use of the three dimensional structure of DACS, classified in class 702, subclass 19.
 - V. Claims 4-5, drawn to use of the three dimensional structure of DAOC/DACS, classified in class 702, subclass 19.
 - VI. Claims 4-5, drawn to use of the three-dimensional structure of "other related enzymes"*, classified in class 702, subclass 19.

Art Unit: 1656

- VII. Claim 8-9, drawn to a gene which codes for the mutant enzyme and a micro-organism containing the gene, classified in class 536, subclass 23.2.
- VIII. Claim 10 drawn to use of the micro-organism containing a mutant gene for making bicyclic β -lactam, classified in class 435, subclass 43.
- IX. Claim 11, 14-15, drawn to use of a mutant enzyme for the preparation of products with bicyclic β -lactam, classified in class 435, subclass 43.
- X. Claim 12, drawn to a method for the preparation of IPNS enzymes in crystalline form for X-ray diffraction studies, classified in class 702, subclass 27.
- XI. Claim 12, drawn to a method for the preparation of a DAOCS enzyme in crystalline form for X-ray diffraction studies, classified in class 702, subclass 27.
- XII. Claim 12, drawn to a method for the preparation of a DACS enzyme in crystalline form for X-ray diffraction studies, classified in class 702, subclass 27.
- XIII. Claim 12, drawn to a method for the preparation of a DAOC/DACS enzyme in crystalline form for X-ray diffraction studies, classified in class 702, subclass 27.
- XIV. Claim 12, drawn to a method for the preparation of "other related enzymes"* in crystalline form for X-ray diffraction studies, classified in class 702, subclass 27.

- XV. Claim 13, drawn to use of the three dimensional structure of IPNS for designing an inhibitor, classified in class 702, subclass 19.
- XVI. Claim 13, drawn to use of the three dimensional structure of DAOCS for designing an inhibitor, classified in class 702, subclass 19.
- XVII. Claim 13, drawn to use of the three dimensional structure of DACS for designing an inhibitor, classified in class 702, subclass 19.
- XVIII. Claim 13, drawn to use of the three dimensional structure of DAOC/DACS for designing an inhibitor, classified in class 702, subclass 19.
- XIX. Claim 13, drawn to use of the three dimensional structure of "other related enzymes"* for designing an inhibitor, classified in class 702, subclass 19.

*The applicant discloses "other related enzymes" from the biosynthetic pathway in Group VI, XIV and XIX. The term "other related enzymes" contains many enzymes each of which being distinct from the others.

3. The inventions are distinct, each from the other because of the following reasons:

Group I are related to Group II, XV by virtue of the protein's structural data being used in the methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Group I is mutually exclusive and not obvious

Art Unit: 1656

variants from Group II, XV because Group I is a protein and Group II, XV are a method of using data of IPNS. Because methods of Group II, XV require a data and not actual protein of Group I, they are not capable of use together.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I and Group III-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the IPNS protein of Group I and methods of Group III-VI are not capable of use together because proteins used in Group III-VI are distinct protein from the Group I with different amino acid sequences. Each method of Group III-VI has different effects because each method uses structural data from different protein, which catalyze a different chemical reaction using different substrate.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using

Art Unit: 1656

different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I and Group VII are related as an enzyme IPNS and a gene that encodes the protein from a penicillin and a cephalosporin biosynthetic pathway, respectively. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the nucleic acid and the protein are related. However, they are distinct inventions because they are wholly different in structure and function. A nucleic acid's structure is comprised of linear, contiguous nucleotides while a protein's structure comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure; the nucleic acid's function is to encode a protein while a protein's function is variable, and in this case, biosynthesis of a penicillin and a cephalosporin. Therefore, a protein of Group I is mutually exclusive and not obvious variants from Group VII. Also Group I cannot be used together with Group VII because they have distinct function; an enzyme of Group I catalyze a chemical reaction and a gene of Group VII encode a protein.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the

Art Unit: 1656

other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I is related to Group VIII by the virtue the micro-organism used in the methods of Group VIII containing a DNA encoding the mutant IPNS of Group I. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the micro organism used in Group VIII is made up of many different materials and composed into very highly ordered structures for the cellular metabolic pathway but Group I is made up of a amino acid and the complexity of structural order is nowhere close to a bacteria. Thus the Group I and Group VIII are mutually exclusive and not obvious variants. The enzyme of Group I can not be used together with Group VIII because of distinct functions; the micro-organism of Group VIII does many chemical processes, replicate itself and useful for amplifying a gene where as the enzyme catalyze a specific chemical reaction.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using

Art Unit: 1656

different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I and Group IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the enzyme of Group I can be used in a process of making protein crystal for x-ray crystallography.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I and Group X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

Art Unit: 1656

process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the enzyme of Group I can be used for the preparation of bicyclic β -lactam of penicillin families.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group I and Group XI-XIV, XVI-XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the IPNS protein of Group I and methods Group XI-XIV, XVI-XIX are not capable of use together because methods of Group XI-XIV, XVI-XIX use structure of distinct protein having different amino acid sequence from the protein of Group I. Each method of Group XI-XIV, XVI-XIX has a different mode of operation for crystallization or designing an inhibitor because each method uses an actual protein or structural data from a different protein of Group I

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different

Art Unit: 1656

classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group II, VIII-X are related to each other by virtue of the method of using data describing an IPNS protein a) encoded by a gene used in the micro-organism of Group VIII-X and b) used in the methods of Group IX and X. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP 806.05(j). In the instant case, Group II use a three dimensional structure data in a computer. Group VIII uses a micro-organism. Group XI uses a mutant enzyme. Group IX uses actual enzymes for crystallization. Therefore, each Group is mutually exclusive from each other Group because each Group has distinct method steps and materials from other Groups as described above. Group II is not capable of use together with Group VIII-X because of distinct function. Group II has a function of modifying a second enzyme whereas all other methods of Group VIII-X have a function of making products.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each

Art Unit: 1656

Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group II are related to Group XV by virtue of the method of using same data describing an IPNS protein. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP 806.05(j). In the instant case, Group II use a three dimensional structure data in a computer. Group IX uses simulation of small molecules to make possible inhibitors. Each Group is mutually exclusive from each other Group because each Group has distinct method steps and materials from other Groups as described above. Group II is not capable of use together with Group XV because of distinct function. Group II has a function of modifying a second enzyme whereas Group XV has a function designing an inhibitor.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group VIII-X are related to Group XV Group II, VIII-X by virtue of the method of molecular simulations using data describing an IPNS protein a) encoded by a gene used in the micro organism of Group VIII-X and b) used in the methods of Group IX and X. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP 806.05(j). In the instant case, Group XV use a three dimensional structure data in a computer for docking simulations of small molecules. Group VIII uses a micro-organism. Group XI uses a mutant enzyme. Group IX uses actual enzymes for crystallization. Therefore, Group VIII-X is mutually exclusive from Group XV because each Group has distinct method steps and materials as described above. Group VIII-X are not capable of use together with Group XV because of distinct function. Group XV has a function of designing inhibitors whereas methods of Group VIII-X have a function of making products.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group II, VIII-X, XV and Group III-VI, XI-XIV, XVI-XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, methods of using a structure, a protein or a gene of Group II, VIII-X, XV and methods III-VI, XI-XIV, XVI-XIX are not capable of use together because methods of Group III-VI, XI-XIV, XVI-XIX either use a distinct protein or use structure of a distinct protein compared to IPNS used in methods of Group II, VIII-X, XV. Each method of Group III-VI, XI-XIV, XVI-XIX has a different effect from methods of Group II, VIII-X, XV because each methods of Group III-VI, XI-XIV, XVI-XIX uses either distinct protein or distinct structural data from methods of Group II, VIII-X, XV.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group II are related to Group VII by virtue of the method of II using data describing a protein encoded by the gene of VII. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP 806.05(j). In the instant case, Group II and

Art Unit: 1656

Group VII are mutually exclusive and not obvious variant from each other because the method steps and materials used in Group II is distinct and does not use a nucleic acid of Group VII. Group II and Group VII are not capable of use together by the virtue of distinct functions; Group II has a function of displaying three-dimensional protein structures whereas a mutant gene of Group VII encodes a protein.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group III-VI and Group VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, methods of using protein structures of Group III-VI neither make nor use the gene of Group VII because methods of Group III-VI either use a different protein or use different protein structure from the protein encoded by the gene of Group VII.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each

Art Unit: 1656

Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group III, XI, XVI are related to each other by virtue of methods of using DAOCS protein and using data describing protein structure. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP 806.05(j). In the instant case, Group III uses a data of DAOCS three-dimensional structures in a computer. Group XI uses an actual DAOCS enzyme for crystallization; Group XVI uses molecules simulation to make inhibitor. Each Group is mutually exclusive from each other Group because of distinct method steps and materials as described above. Group III has a function of modifying a second enzyme whereas all other methods of Group XI, XVI have a function of making products or designing an inhibitor. Therefore, each Group is not capable of use together with any other Group because of distinct functions.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group III, XI, XVI and Group IV-VI, VIII-X, XII-XV, XVII-XIX are unrelated.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, methods of using DAOCS protein or DAOCS structure of Group III, XI, XVI and methods Group IV-VI, VIII-X, XII-XV, XVII-XIX are not capable of use together because methods of Group IV-VI, VIII-X, XII-XV, XVII-XIX use distinct proteins, a micro organism with distinct gene or distinct protein structures from DAOCS. Each method of Group IV-VI, VIII-X, XII-XV, XVII-XIX also has a different effect from methods of Group III, XI, XVI because each method uses distinct structural data distinct from the one used in Group III method.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group IV, XII, XVII are related to each other by virtue of methods of using DACS proteins and using data describing protein structure. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP 806.05(j). In the instant case, Group IV uses

a data of three-dimensional DACS structure in a computer. Group XII uses an actual enzyme for crystallization; Group XVII uses molecules simulation to make inhibitor. Each Group is mutually exclusive from each other Group because of distinct method steps and materials as described above. Group IV has a function of modifying a second enzyme whereas all other methods of Group XII, XVII have a function of making products or designing an inhibitor. Each Group is not capable of use together with any other Group because of distinct functions as described above.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group IV, XII, XVII and Group V-VI, VIII-XI, XIII-XVI, XVIII-XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, methods of using DACS or DACS structure of Group IV, XII, XVII and methods Group V-VI, VIII-XI, XIII-XVI, XVIII-XIX are not capable of use together because methods of Group V-VI, VIII-XI, XIII-XVI, XVIII-XIX use a distinct protein, a micro organism with distinct gene or a distinct protein structure data compared to DACS used in method of Group IV, XII, XVII. Each method of Group V-VI, VIII-XI, XIII-XVI, XVIII-XIX has a different effect from the method of Group IV, XII, XVII

because each method uses distinct protein or distinct structural data from the one used in Group IV, XII, XVII.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group V, XIII, XVIII are related to each other by virtue of the method of using DAOC/DACS proteins and using data describing protein structure. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP 806.05(j). In the instant case, Group V uses a three dimensional structure data of DAOC/DACS in a computer. Group XIII uses an actual enzyme for crystallization. Group XVIII uses molecules simulation to make inhibitor. Each Group is mutually exclusive from any other Group because of distinct method steps and materials from any other Group as described above. Group V has a function of modifying a second enzyme whereas other methods of Group XIII, XVIII have a function of making products or designing an inhibitor. Therefore, each Group is not capable of use together with any other Group because of distinct function as described above.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group V, XIII, XVIII and Group VI, VIII-XII, XIV-XVII, XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, methods of using DAOC/DACS proteins or protein structure of Group V, XIII, XVIII and methods Group VIII-XII, XIV-XVII, XIX are not capable of use together because each method of Group VIII-XII, XIV-XVII, XIX use a distinct protein, a micro organism with distinct gene or a distinct protein structure from the DAOC/DACS used in methods of Group V, XIII, XVIII. Each method of Group VIII-XII, XIV-XVII, XIX has a different effect from methods of Group V, XIII, XVIII because each method uses structural data distinct from the one used in Group V, XIII, XVIII.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group VI, XIV, XIX are related to each other by virtue of the method of using "other related enzymes"* and using data describing structure. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP 806.05(j). In the instant case, Group VI use a protein structure data of "other related enzymes"* in a computer. Group XIV use an actual enzyme for crystallization. Group XIX uses molecules simulation to make inhibitor. Group VI, XIV, XIX are mutually exclusive from each other because of distinct method steps and materials as described above. Group VI has a function of modifying a second enzyme whereas all other methods of Group XIV, XIX have a function of making products or designing an inhibitor. Each Group is not capable of use together with any other Group because of distinct function as described above.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group VI, XIV, XIX and Group VIII-XIII, XV-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and §

Art Unit: 1656

806.06). In the instant case, methods of using "other related enzymes"* and their structure of Group VI, XIV, XIX and methods Group VIII-XIII, XV-XVIII are not capable of use together because methods of Group VIII-XIII, XV-XVIII use a distinct protein, a micro organism containing distinct gene or a distinct protein structure data compared to "other related enzymes"* of Group VI, XIV, XIX. Each method of Group VIII-XIII, XV-XVIII has a different effect from the method of Group VI, XIV, XIX because each method uses distinct protein or distinct structural data from Group VI, XIV, XIX.

Because these inventions are distinct for the reasons given above, because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group VII and Group VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the micro-organism of Group VII can be used for the host cell in the recombinant cloning.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group VII and Group IX-X, XV are related by the virtue of the method of Group IX-X, XV uses a protein or a protein structure encoded by the gene of VII. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP 806.05(j). In the instant case, the gene of Group VII and the methods of Group IX-X, XV are mutually exclusive and not obvious variants because the methods of Group IX-X, XV do not use the gene of Group VII. The gene of Group VII has function of encoding a protein whereas the method of Group IX-X, XV either function of making the product, protein crystals or inhibitor. Therefore, Group VII and Group IX-X, XV have distinct function and mode of operation.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the

Art Unit: 1656

other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Group VII and Group XI-XIV, XVI-XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the mutant IPNS gene of Group VII and methods Group XI-XIV, XVI-XIX are not capable of use together because methods of Group XI-XIV, XVI-XIX use a distinct protein, a micro organism containing distinct gene or a distinct protein structure from the protein that can be encoded by the gene of Group VII. Group VII has a function of encoding a protein whereas all other methods of Group XI-XIV, XVI-XIX have a function of making protein crystals or designing an inhibitor. Thus, Group VII and Group XI-XIV, XVI-XIX have distinct functions as described above.

Because these inventions are distinct for the reasons given above, because the inventions have acquired a separate status in the art as shown by their different classification, and because the search required for any one Group is not required for the other Group as each Group requires a different non-patent literature search using different keywords due to each Group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Election of Species

4. This application contains claims directed to the following patentably distinct species: In Group I, each IPNS protein complex with a different substrate is distinct species in Claims 2-3. In addition, each mutant enzyme in Claims 6-7 is distinct species.

These species are related to IPNS enzyme involved in a penicillin and cephalosporin biosynthetic pathway. However, the related species are distinct because they do not overlap in scope and are not obvious variants. For example, each substrate has distinct chemical structure requiring a separate search for each substrate. The IPNS protein containing a different substrate has distinct chemical composition. Therefore, species of Claims 2-3 are distinct evidenced by a distinct chemical composition, a distinct structures of the claimed inventions. In addition to their distinctness, the search of each complex requires different keywords search, thus searching species of claims 2-3 together would impose a serious search burden on the examination process.

Species of Claims 6-7 are related to mutant IPNS enzyme involved in a penicillin and cephalosporin biosynthetic pathway. However, each mutant has different sequence and chemically distinct. Therefore, each mutant is a distinct product, thus searching all mutants in Claims 6-7 together would impose a serious search burden on the examination process.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution from Claims 2-3 and Claims 6-7 on the merits to which the claims shall be

Art Unit: 1656

restricted if no generic claim is finally held to be allowable. Currently, Claim 1 of the Group I is a generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Notice of Possible Rejoinder

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

Art Unit: 1656

whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

Art Unit: 1656

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander D. Kim whose telephone number is (571) 272-5266. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alexander Kim
28 February 2006


KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER